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Congress of the United States
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January 10, 2022

Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Acting Commissioner Woodcock,

I write to inquire about the U.S. Food and Drug Administration's (FDA) recent proposal to release data pertaining to the approval of the Pfizer/BioNTech coronavirus vaccine over the course of over 55 years.

In August 2021, a Freedom of Information Act (FOIA) request was filed by the nonprofit group Public Health and Medical Professionals for Transparency (PHMPT) seeking all documents and data the FDA has on the Pfizer vaccine, including clinical trial data, correspondence between the FDA, BioNTech, and Pfizer, and information on side effects. After refusing to expedite the request, PHMPT sued, and in November, the FDA requested releasing the information over the course of 55 years. On January 6, 2022, a federal judge in Texas ruled the FDA must release 55,000 pages of documents per month, resulting in the full release of information by the end of 2022.

The original timeline requested by the FDA was absolutely unacceptable and highlights the FDA's constant inability to meet the 20-day FOIA response deadline set by Congress. According to the most recent Department of Health and Human Services (HHS) FOIA report, there were over 2,800 backlogged requests at the end of FY 2020.[1] This, in conjunction with the FDA's consistent overuse of redactions in the public health documents it does release, has led to a lack of transparency and public trust in the FDA. Information on life-saving medical treatments like the Pfizer Covid-19 vaccine must be released with limited redactions so the public has confidence in FDA decisions.

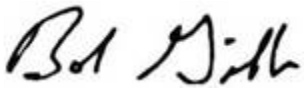
I therefore respectfully ask you to respond to the following questions:

- Will the FDA commit to following the court order of releasing 55,000 pages of documents per month?

[1] https://www.hhs.gov/foia/reports/annual-reports/2020/index.html

- Will the FDA commit to making limited redactions to the released documents?
- Does the FDA have a plan to increase transparency surrounding its approval process?

Sincerely,



Bob Gibbs
Member of Congress